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ABSTRACT:

An improved intravenous administration set is provided. The intravenous administration set (10) has nonremovable markings (34) positioned such that the user may identify a particular IV set at its point of attachment to a fluid source and immediately determine whether a Y-site (26), adapter (22) or other fluid entry or exit port is a component part of the same IV set and immediately distinguish one set from another. The markings (34) advantageously may be provided on the surface of the hardware of the IV sets or may consist of color tint added directly to the material from which the hardware is made. Kits having a plurality of IV sets, each with different markings, are also provided.

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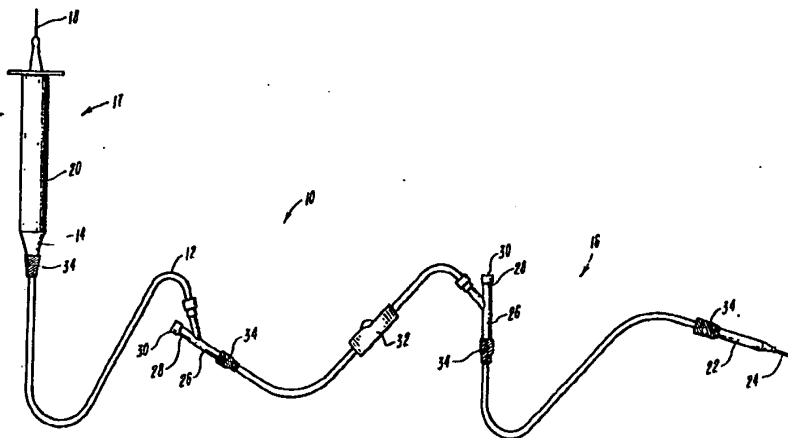
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(54) Title: IMPROVED INTRAVENOUS ADMINISTRATION SET



(57) Abstract

An improved intravenous administration set is provided. The intravenous administration set (10) has nonremovable markings (34) positioned such that the user may identify a particular IV set at its point of attachment to a fluid source and immediately determine whether a Y-site (26), adapter (22) or other fluid entry or exit port is a component part of the same IV set and immediately distinguish one set from another. The markings (34) advantageously may be provided on the surface of the hardware of the IV sets or may consist of color tint added directly to the material from which the hardware is made. Kits having a plurality of IV sets, each with different markings, are also provided.

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IMPROVED INTRAVENOUS ADMINISTRATION SET

This invention relates to intravenous administration sets.

BACKGROUND OF THE INVENTION

Intravenous administration sets (IV sets) are used to deliver sterilely therapeutic solutions from a container to a patient. An IV set includes flexible tubing having a hollow spike at one end for puncturing and providing passage from a container of therapeutic solution and an adapter at the opposite end for providing a connection to a needle, catheter, or the like which accesses a patient's blood vessel. The container typically is hung from an IV pole and the therapeutic solution is either gravity fed or mechanically pumped (to regulate precisely the volume of infusion) into a patient.

IV sets usually have injection ports (Y-sites) attached along the length of flexible tubing. Medications or the like may be injected repeatedly into the flexible tubing via the Y-site and carried to the patient's blood stream, without repeated puncture of the patient's skin. For instance, a patient receiving intravenous hydration with saline

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may require a dose of intravenous antibiotics which may be "piggy-backed" into the Y-site of the hydration fluids. Similarly a patient having a transfusion reaction may require an IV bolus of meperidine to stop rigors, which bolus may be injected through a Y-site.

There are many medical situations requiring the simultaneous infusion of multiple therapeutic solutions into a single patient; it is common to use multiple IV sets with a single patient, each IV set delivering a different solution. In some cases separate IV sets are needed because the medications being infused are chemically incompatible and cannot be safely infused together. In other cases the different solutions cannot be mixed because one solution and intravenous line must be "dedicated," that is, used exclusively for the nutrition solution to prevent infections. Therefore, it may be necessary for a doctor or a nurse to select from several IV sets the one set that is safe to receive an injection of a particular therapeutic substance. For instance, an oncology patient may have three fluids infusing: 1. morphine; 2. artificial nutrition; and 3. an antibiotic. The patient may require repeated bolus injections of a diuretic that may be compatible with only one of the infusing fluids. Thus a physician or a nurse will have to

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identify from among the three infusing IV sets the proper set and the proper Y-site for injecting the diuretic. In many circumstances, such as emergencies and cardiac arrest situations, time is of the essence and the determination of the correct IV set for injecting a particular drug must be made instantaneously.

The current methods for identifying the correct IV sets and Y-sites on that set for medication delivery are inadequate. Usually the IV tubing is "fished," followed from its connection to a solution container through a tangle of IV tubing to the injection site at the patient's skin. This "fishing" procedure is time consuming and can easily result in mistakes. Alternatively, hospitals may have colored tape available that is occasionally applied to each of the IV sets at various locations to distinguish one IV set from another. This latter practice is far from universal, usually occurring in those instances when the IV set is being used in an elective procedure and there is plenty of time, prior to the procedure, to set up the IV tubing. Given time constraints, the tape labelling is rarely performed on hospital wards and almost never during an emergency. Even when it is followed, mistakes can occur when tape is improperly applied to the wrong tubing sets.

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SUMMARY OF THE INVENTION

It is an object of the invention to provide indicia for IV sets, which indicia overcome the foregoing inadequacies characteristic of the prior art.

It is another object of the invention to provide IV sets having component parts that are easily identified and distinguished when multiple IV sets are used with a single patient.

It is a further object of the invention to provide indicia for IV sets that facilitate the quick administration of solutions to a patient in code situations and that reduce the risk of administration of a solution into the wrong access port.

These and other objects are achieved by the invention which provides identification indicia on otherwise conventional IV sets. The indicia are nonremovable and may be symbols, bars, rings, stripes, see-through tinting, and the like, preferably colored. The indicia are positioned to distinguish one particular IV set from another. The user identifies a particular IV set close to its point of attachment to a fluid solution or at the connection to the patient, and then by matched indicia, not "fishing," the user can immediately

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identify the Y-site, adapter, or other fluid entry or exit ports as a component part of the same IV set or of a different set. Ideally, the indicia may be provided on the surface of the "hardware" of the IV sets, for instance on the drip chamber, the multiple Y-sites, and the tapered adapter that attaches to the needle or catheter accessing the patient. The indicia may also be a color tint added directly to the material from which the hardware of the IV set is made. Alternatively, the hardware may be clear as it is currently while the flexible IV tubing itself may be marked or color tinted.

The IV sets of the invention may be individually packaged, the common, coding indicia being included or applied prior to packaging and in pre-sterilized condition. Each package itself may include external markings indicating the coding indicia of the IV set contained within that package. A group of the individual packages may be provided in a larger container also including a marking indicating the coding indicia of the contained IV sets.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates an IV set of the invention;
Fig. 2 illustrates two IV sets of the invention attached to the same patient;

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Fig. 3 illustrates an embodiment of the identification indicia of the invention applied to a drip chamber;

Fig. 4 illustrates another embodiment of the identification indicia of the invention applied to a drip chamber; and

Fig. 5 illustrates yet another embodiment of the identification indicia of the invention applied to a drip chamber.

DETAILED DESCRIPTION OF THE DRAWINGS

The IV set of Fig. 1 illustrates the invention. The IV set 10 includes flexible tubing and substantially rigid hardware attached to the tubing at various locations. The flexible tubing 12 has a fluid entry end 14 and a fluid exit end 16. The fluid entry end 14 is attached to a hollow spike adapter/drip chamber arrangement 17. This arrangement includes a hollow spike 18 for puncturing and providing fluid access to a container of therapeutic solution. The spike 18 is in fluid communication with a drip chamber 20 which allows visualization of the flow rate of fluid through the IV set. The drip chamber 20 in turn is connected to the fluid entry end 14 of the flexible tubing 12. The fluid exit end 16 of the flexible tubing 12 is

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attached to a coupling means or adapter 22 which terminates in a luer taper 24. This adapter provides for quick mechanical attachment to needles, manifolds, catheters and the like.

Attached along the length of flexible tubing 12 are Y-sites 26. These Y-sites 26 have an injection port 28 closed by a resealable septum 30. A needle may be introduced through the septum 30 to allow repeated introduction of medication and the like into the patient via the lumen of the flexible tubing without requiring repeated puncture of the patient's skin. Fluid control means 32 also is provided along the length of flexible tubing 12 to control the flow rate of liquid through the flexible tubing.

The IV set as described above is conventional and does not form a part of this invention.

The invention involves the indicia 34 shown in Fig. 1 as rings fully encircling each of the drip chamber 20, the Y-sites 26, and the adapter 22. In a preferred embodiment, the indicia 34 are colored, the indicia 34 on a single IV set all being the same color.

The indicia 34 may be painted, printed, glued or applied to the IV sets by any other means that provides a nonremovable marking, that is, one that is not readily removed during ordinary usage of the

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IV set. In the embodiment shown, the rings are applied as colored, shrink wrap at the junction between the hardware and the IV flexible tubing. Alternatively, the hardware itself may be formed of a tinted but see-through plastic material. When tinting the hardware, it is preferred that the tint be slight so that liquid flow within the hardware still may be observed through the wall of the hardware. If tinting, it is desirable to use a tinting material that does not dissolve from the walls of the hardware when contacted with typical IV solutions and that meets all other necessary requirements of biocompatibility. The flexible tubing also may be tinted, either as a supplement or an alternative to tinting the hardware.

The principal of the invention is illustrated in Fig. 2 wherein like numerals designate like parts, with primes indicating different IV sets. The IV sets 10, 10' are attached to IV solution containers, in this instance a medicament solution container 36 and a nutrient solution container 38. The indicia 34 of IV set 10 are, for example, blue and the indicia 34' of IV set 10' are, for example, red. If it is necessary to introduce a high dose of medicament directly into the flexible tubing at the Y-site 26' of the medicament IV set 10', the physician or nurse may quickly identify the color of

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the indicia 34' on the drip chamber which is located close to the medicament solution container 36, and then select a Y-site with the same color coded indicia 34'. The flexible tubes need not be sorted or "fished." The determination is virtually instantaneous.

Alternatively, the doctor or nurse may be able to identify the medicament dedicated IV set by its location of attachment to the patient. In this instance, the doctor or nurse would identify the indicia 34' on the adapter 22' and then select a Y-site 26' having the same color coded indicia.

Figs. 3-5 illustrate other configurations of the identification system of the invention. In these embodiments, the indicia are stripes (Fig. 3) and bars (Fig. 4). The identification indicia of the invention also may be based upon, for example, the number of markings (Fig. 5), the color of the indicia or by the shape of the indicia. While stripes, rings and bars have been shown, the invention is not limited to these particular symbols which are merely representative.

The IV sets of the invention may be individually packaged, the common, coding indicia being included or applied prior to packaging in pre-sterilized condition. Each package may include a marking indicating the coding indicia of the IV

-10-

set contained therein. Alternatively, a package may be transparent or be provided with a window to allow visualization of the IV set and its coding indicia. A group of individual packages then may be provided in a larger container including a marking indicating the coding indicia of the contained, packaged IV sets. These various forms of package and container markings allow one to ascertain the coding indicia of the contained IV sets without opening the container or package.

A single package also may include a plurality of IV sets, the coding indicia of each IV set differing from one another. For example, a package may contain three IV sets, each set coded to correspond to the color coding of a triple lumen catheter.

Thus, an improved method is provided for reducing error when accessing a Y-site on one of a plurality of IV sets connected to a patient. IV sets are coded, packaged and sterilized. Then, a plurality of these IV sets are selected, each of the IV sets having a unique coding. This plurality of IV sets then is connected to a single patient. The various fluid access ports along the length of tubing then are instantaneously distinguishable and easily traced to the fluid inlet end or fluid outlet end of the tubing.

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It will be understood by one of ordinary skill in the art that various modifications may be made to the embodiments described without departing from the scope and spirit of the invention. The specification then is to be interpreted in an illustrative and not limiting sense.

What I claim is:

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CLAIMS

1. An intravenous administration set for administering a solution to a patient comprising,
a spike for puncturing and providing a passage into a container of solution,
a chamber in fluid communication with the spike for monitoring flow of solution from the container,
tubing having two ends and being in fluid communication at one end with the chamber for conveying solution from the chamber,
coupling means attached at the opposite end of the tubing,
at least one Y-site attached along the tubing providing fluid access to the tubing at the Y site, and
common coding indicia associated in pre-sterilized condition with said chamber, Y-site and coupling means.

2. In a packaged intravenous administration set having fluid delivery tubing with two ends, a spike/drip chamber attached at one end, an adapter attached at the opposite end, and a Y-site attached along the tubing, the improvement comprising,

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common, distinctive coding indicia associated with said Y-site, said spike/drip chamber and said adapter.

3. The improvement of claim 2 wherein said coding indicia is permanently adhered in pre-sterilized condition to the spike/drip chamber, Y-site, and adapter.

4. The improvement of claim 2 wherein the coding indicia is located at the tubing.

5. The improvement of claim 2 wherein the coding indicia comprises color-tinted tubing.

6. The improvement of claim 2 wherein the coding indicia comprises color-tinting material forming at least a portion of the Y-site, the spike/drip chamber and the adapter.

7. In an intravenous administration set having flexible tubing defining a fluid receiving a end and having a Y-site located remote from the fluid receiving end, the improvement comprising, first shrink wrap means applied close to the fluid receiving end providing first coding indicia, and

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second shrink wrap means applied close to the Y-site providing second indicia corresponding to the first indicia.

8. In an intravenous administration set having flexible tubing defining a fluid receiving end and having a Y-site located remote from the fluid receiving end, the improvement comprising, first hardware located at or near the fluid receiving means, the first hardware being marked by a first symbol, and

second hardware located remote from the first hardware, the second hardware being marked by a second symbol corresponding to the first symbol.

9. A container having contained therein a plurality of packaged IV sets, each IV set including hardware having common coding indicia associated therewith, and said container having associated therewith means indicating the coding indicia of the IV sets within the container.

10. A container as claimed in claim 9 wherein each of the IV sets has a fluid receiving end and a penetrable fluid access means and wherein said common coding indicia is located close to the fluid receiving end and close to the penetrable fluid access means.

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11. A container as claimed in claim 10 wherein the plurality of IV sets all have the same coding indicia.

12. A container as claimed in claim 10 wherein the coding indicia of at least one IV set differs from the coding indicia of another of the IV sets.

13. A container as claimed in claim 10 wherein each IV set is individually packaged, and each package includes means indicating the coding indicia of the IV set contained therein.

14. A container as claimed in claim 13 wherein said means indicating the coding indicia comprises means allowing visualization of the coding indicia on the IV set.

15. A container having contained therein a plurality of individually packaged IV sets, each IV set including hardware having common coding indicia associated therewith, and each package including a marking indicating the coding indicia of the IV set contained therein.

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16. A package having contained therein a plurality of IV sets, each IV set including hardware having common coding indicia associated therewith, and wherein all of the IV sets in the package have different coding indicia.

17. A windowless package having contained therein an IV set including a fluid receiving end and a penetrable fluid access means and having common coding indicia associated with the fluid receiving end and the fluid access means, the windowless package having marked thereon means indicating the coding indicia of the IV set within the package.

18. A method for reducing error when accessing a Y-site on one of a plurality of IV sets connected to a single patient comprising,

providing a plurality of packaged IV sets, each of the packaged IV sets having coding indicia associated with its Y-site, the coding indicia being different for each IV set,

attaching the differently coded IV sets to a single patient,

selecting one of the Y-sites based upon its coding indicia, and

accessing that Y-site via a needle.

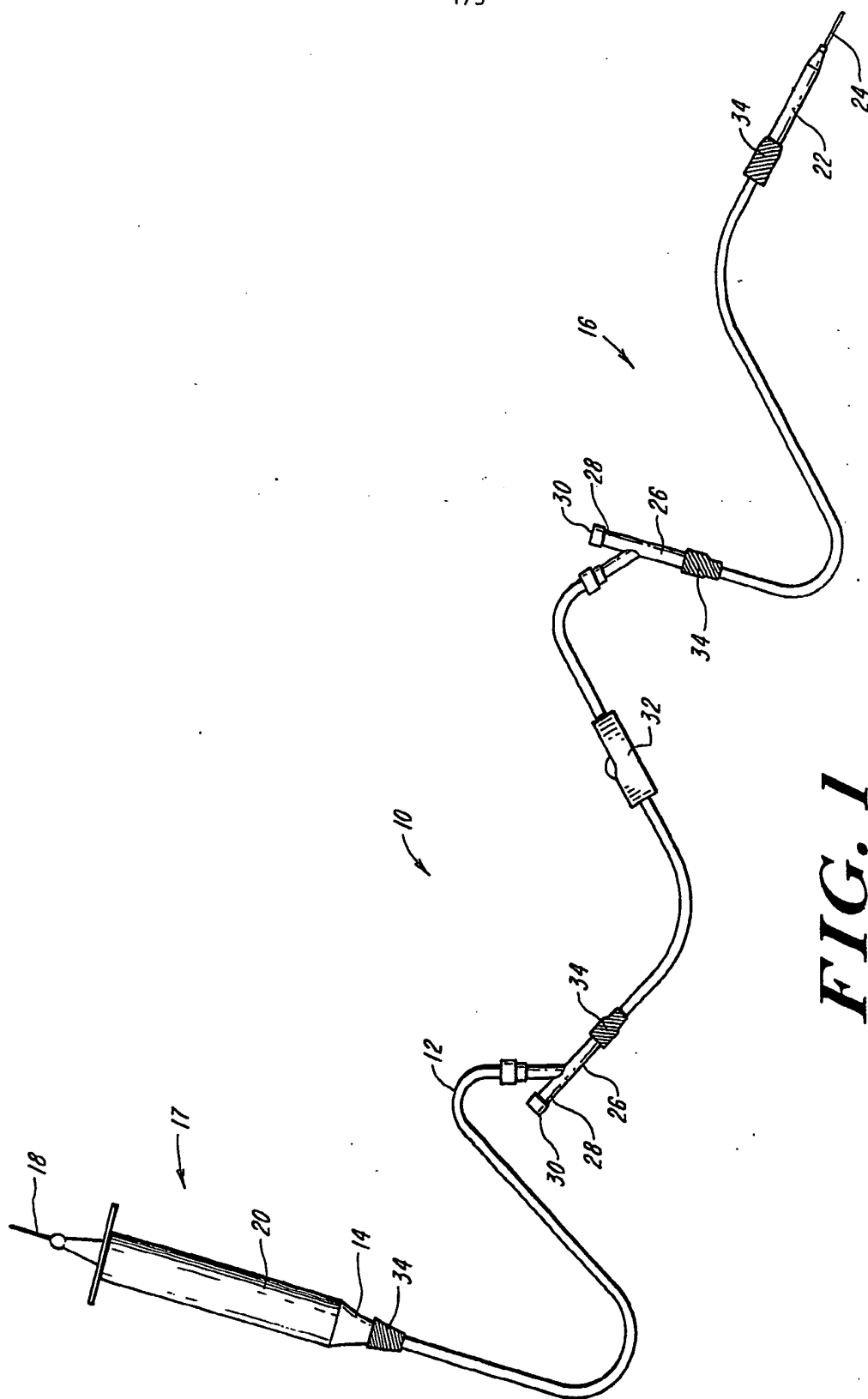
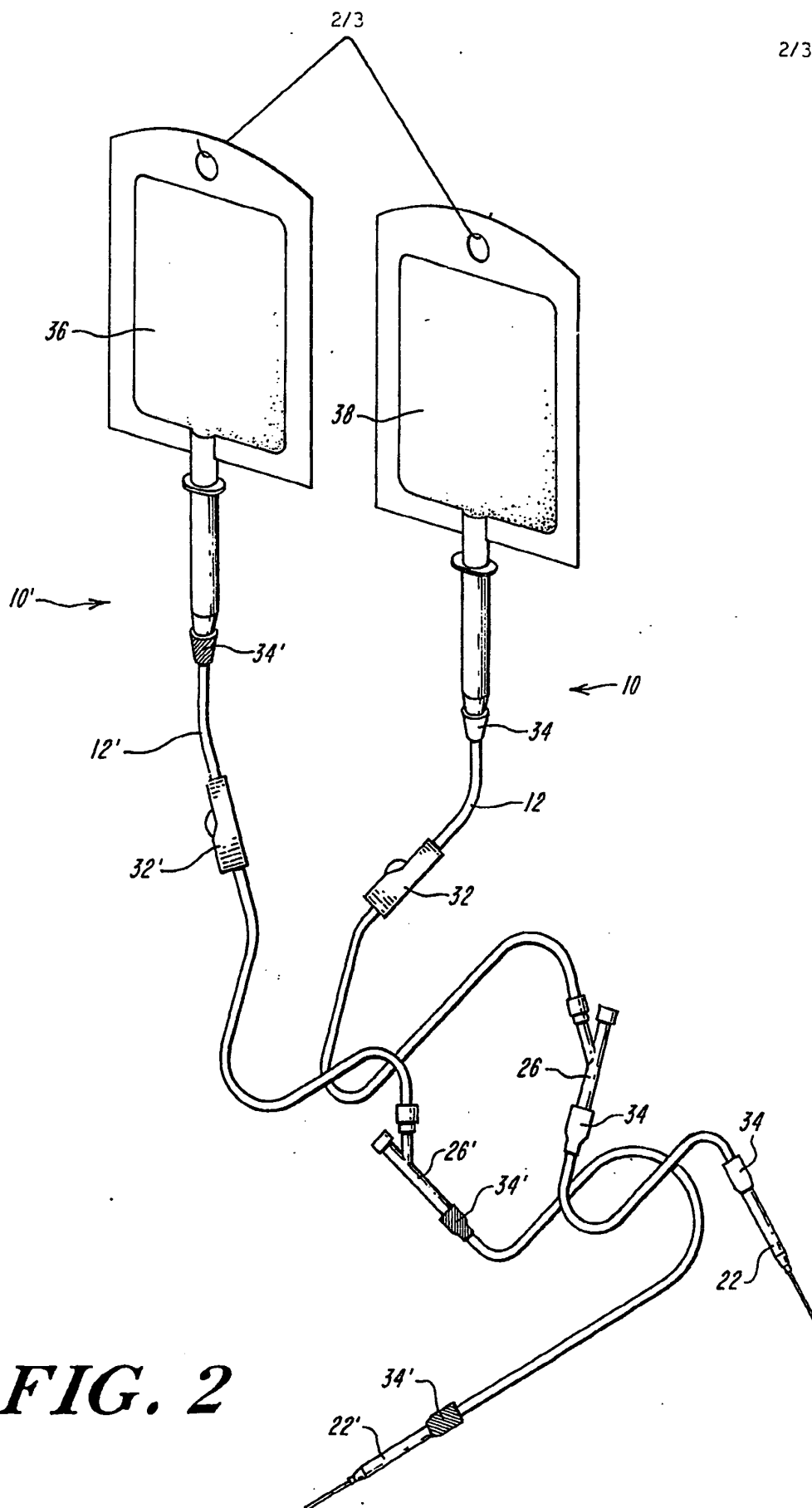


FIG. 1

**FIG. 2**

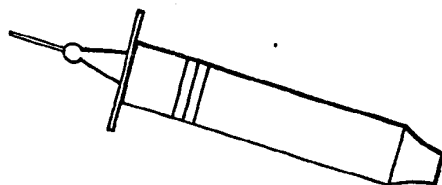


FIG. 5

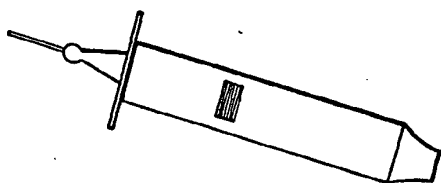


FIG. 4

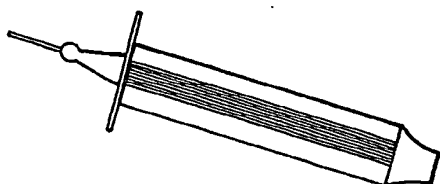


FIG. 3

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US90/06060

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ¹

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61B 19/00

US CL.: 604/403

II. FIELDS SEARCHED

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Classification System

Classification Symbols

US 604/403, 404, 408, 80, 111, 262, 905

Documentation Searched other than Minimum Documentation
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III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴

Category ⁹	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
X	US, A, 4,654,026 (UNDERWOOD) 31 MARCH 1987 See the entire document.	1,8
Y	US, A, ,4654,026 (UNDERWOOD) 31 MARCH 1987 See the entire document.	2-6,9-18
Y	US, A, 4,693,707 (DYE) 15 SEPTEMBER 1987 See the entire document.	7
A	US, A, 2,896,619 (BELLAMY, JR.) 28 JULY 1959 See the entire document.	1-18
A	US, A, 4,692,150 (CIANCI et al.) 08 SEPTEMBER 1987 See the entire document.	1-18
A	US, A, 4,795,429 (FELDSTEIN) 03 JANUARY 1989 See the entire document.	1-18

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"Z" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search ²

21 NOVEMBER 1990

Date of Mailing of this International Search Report ²

12 FEB 1991

International Searching Authority ¹

ISA/US

Signature of Authorized Official ¹⁹

Fm

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